REMARKS

Claims 1-26 are pending. The claims stand rejected. In view of the remarks presented below, Applicants respectfully request reconsideration and withdrawal of the rejections set forth in the June 6, 2008 Office Action.

The claims of the present invention are directed to sustained-release dosage forms of pramipexole, dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of a particular claimed value. The Office Action has rejected the claims under 35 U.S.C. 112, ¶2, 102, and 103, as allegedly being indefinite, anticipated and obvious in view of certain cited art, respectively. Applicants respectively submit that the claimed term "tensile strength" has been misconstrued in the Office Action, and has thus, been accorded no weight when comparing the present claims to the prior art. Applicants respectfully submit that the term "tensile strength" has a clear and definite meaning to one having ordinary skill in the art, and is a distinguishing feature of the present invention.

Rejection Under 35 USC § 112, ¶ 2

Claims 1-26 have been rejected under 35 U.S.C. § 112, ¶ 2 for allegedly being indefinite. In particular, the claims, which recite a starch having a particular tensile strength, stand rejected because the term "tensile strength" is allegedly indefinite. According to the Office Action, because "tensile strength is an intensive property," the claims must specify the exact manner in which the sample was made and the exact manner in which the tensile strength was measured. In addition, the Office Action alleges that it is "unclear" whether the term "tensile strength" refers to the entire tablet, or just the starch alone. Applicants respectfully submit that the claims are not indefinite for the reasons that follow.

As a preliminary matter, Applicants note that the claims refer to sustained-release tablets that comprise, *inter alia*, a starch having a minimum tensile strength requirement "***at a solid fraction representative of the tablet***." Applicants respectfully submit that the claim phrase "at a solid fraction representative of the tablet" addresses the issues raised in the Office Action. First, the term "solid fraction" is specifically defined in the present application as "the ratio of absolute to apparent density of a *starch* compact." *See* App. at p. 4, ¶ [0019] (emphasis added). A "compact" is defined as a "compressed tablet," that "consist[s] *only* of a sample of *starch*." *See id.* (emphasis added). The specification then discloses that the tensile strength determination is based on the *starch compact* as defined above. *See, e.g., id.* at ¶¶ [0045]-[0060]. Accordingly, from the description provided in the specification, one having ordinary skill in the art would understand that the value of tensile

strength is based on the starch compact – which the specification explains is a compact of starch alone. Accordingly, the claims are not indefinite.

The Office Action further alleges that the claim term "tensile strength" is indefinite because the claims do not specify how the starch compact was formed, under what conditions the compact was compressed, or under what conditions the tensile strength was measured. In this regard, the Office Action requests that the claims be amended to include such parameters (*e.g.*, the exact compression force used to make the compact, etc.). Applicants, however, respectfully submit that a rejection on such basis is without merit, and that restriction of the claims in the manner suggested would unduly, and improperly, limit the proper scope of the invention. Once again, Applicants submit that the key to understanding the present invention is the claim phrase "at a solid fraction representative of the tablet." Indeed, the specification directs one having ordinary skill in the art to "prepar[e] a series of compacts of the starch sample," using "various degrees of compression force to provide compacts having a range of solid fraction." The specification then informs one of skill in the art that solid fractions of about 0.8 are representative of sustained release formulations. The claims, which require a particular tensile strength, *also* specify that the tensile strength must be a solid fraction *representative of the tablet* (which, in the case of the present invention, is a sustained-release tablet). Accordingly, one skilled in the art is directed to making various compacts of starch samples, determining which of the samples are representative of a sustained-release tablet (using the guidance of about 0.8 as provided by the specification), and then measuring the tensile strength of such, representative, compacts.

Finally, with respect to measuring the value of tensile strength, the specification provides that the measurement can be made using "any suitable test." *See id.* at ¶ [0046]. The application then goes on to provide several different examples of tests that can be used – e.g., "triaxial test"; "4 second dwell time test"; and "90 second dwell time test." *See id.* at ¶¶ [0046] – [0061]. The tensile strength of six different lots of starch samples were each tested three times – using the triaxial, 4 second dwell time, and 90 second dwell time tests. The results, which are provided in Tables 1 and 2 of the specification, demonstrate that the value for tensile strength of each respective lot was essentially the same under the different tensile strength tests. Accordingly, the claims are not indefinite. Indeed, under applicable precedent of the Federal Circuit, the failure to specify a method to be used in measuring a claimed feature does not render the claims indefinite – where all of the conventional methods used to measure the claimed feature produce essentially the same results. *See PPG*

Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1563 (Fed. Cir. 1996). Because, in the context of the present invention, the values obtained for tensile strength were comparable using different, conventional measuring tests, the rejection should be withdrawn under *PPG Industries*.

Rejections under 35 U.S.C. §102

The Office Action has maintained its rejections of the claims as allegedly being anticipated by United States Patent No. 6,277,875 (hereinafter "Holman"), and as allegedly being anticipated by United States Patent Application Publication No. U.S. 2003/01800352) (hereinafter "Patel"). The Office Action, however, admits that neither reference discloses the use of a starch having the particular claimed value of tensile strength as described in the present invention. Rather, the Office Action admits that because the term "tensile strength" is indefinite, the limitation was essentially ignored when searching for prior art. Because, as the Applicants have shown above, the term "tensile strength" is not indefinite, the limitation must be considered when comparing the claimed invention to the cited art. Consequently, because neither Holman nor Patel disclose sustained-release pramipexole compositions comprising, *inter alia*, a starch with the claimed tensile strength value, neither can anticipate the present claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections Under 35 USC § 103(a)

Claims 1-26 have been rejected as allegedly being obvious under 35 U.S.C. §103(a) in view of (a) Holman in view of Michaud (EP 0933079); (b) Patel in view of Michaud; and (c) Holman in view of Khan (U.S. Pat. No. 5,656,296) and Petrus (WO 00/59477) and in further view of Michaud. In connection with each of the rejections, of all the references cited, the Office Action alleges that only Michaud teaches "pregelatinized starch, which has a tensile strength greater than [A]pplicant's lower limit." In this regard, the Office Action relies ***solely*** on Michaud in an effort to establish that "compressed formulations comprising pregelatinized starch within Applicants' claimed tensile strength range were already known in the art."

Assuming, for the sake of argument only, that Michaud does disclose the use of high-tensile strength starches for use in tablets, Applicants previously pointed out that such disclosure would still be insufficient to render the presently claimed invention obvious because Michaud is directed to ***rapidly-dissolving*** tablets. Accordingly, one having ordinary

skill in the art would not attempt to make a sustained-release tablet formulation using the rapidly-disintegration techniques described in Michaud. Moreover, assuming for the sake of argument only, that one would have done so, it could not have been done with the expectation that the combination would reasonably result in a sustained release tablet, particularly in view of the fact that Michaud describes:

> A directly compressible starch consisting in an intense white free-flowing powder showing both excellent compression profile and e***xtremely good disintegration properties***. ***This starch is especially designed*** to be used as a binder in direct compression processes where it yields very hard white tablets at relatively low compression forces. ***Tablets resulting from the compression of the above mentioned starch disintegrate in an aqueous medium at a very high speed***.

Michaud, at p. 1 (emphasis added). Accordingly, Applicants respectfully submit that there is no reasonable expectation of success in applying the teaching of Michaud to any of the other cited references to arrive at the instant application. Thus, a *prima facie* case of obviousness cannot be made, and the rejection should be withdrawn.

The Office Action suggests that the above description is insufficient to overcome the challenge of obviousness, see page 13. Indeed, the Office Action appears to place the burden on the Applicant to demonstrate "where within the Michaud reference, it states that all tablet forms described within are immediate release." Page 13. In response, Applicants respectfully submit that because Michaud teaches that "[t]ablets resulting from the compression of [its] starch disintegrate in an aqueous medium at ***very high speeds***," one skilled in the art would interpret that passage as ***teaching away*** from using the starch of Michaud when formulating a sustained-release tablet, where prolonged or slower dissolution times would be required. Consequently, if one of ordinary skill in the art would find no motivation to combine Michaud with any of the other cited references, or would have no reasonable expectation that the starch of Michaud could be used in a sustained-release tablet, then Michaud cannot be combined with such references for purposes of maintaining the obviousness rejection. Moreover, since none of the other references disclose the use of a high-tensile strength starch, Applicants respectfully submit that the rejection must be withdrawn.

Conclusion

In view of the remarks above, Applicants respectfully submit that the pending claims are fully allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the

Examiner is invited to contact applicants' undersigned attorneys at the telephone number provided.

The Commissioner is hereby authorized to charge any fees required, including the RCE feed under 37 CFR 1.17(e), or to credit any overpayment to Deposit Account No. 16-1445.

Respectfully submitted,

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